

Appl. No. 10/620,514  
Docket No. D0287 NP

#### REMARKS

In the present amendment, claims 1-4, 7, 11-13, and 20 have been amended, and claims 14-17 have been canceled. After entry of these amendments, claims 1-13 and 18-20 will be pending.

The amendment to claims 1 and 11 concerning the feature that the androgen receptor nucleic acid is expressed in said mouse in at least one tissue selected from the group consisting of lung, heart, liver, testis, bone, prostate, and kidney, such that said mouse has enhanced expression of androgen receptor relative to a wild type mouse in said at least one tissue is supported in the specification at page 11, lines 19-25, and page 14, lines 15-21. It is believed that the amended claims are supported by the originally filed application, and that no new matter is added.

Applicants' representative appreciates the courtesies extended by Examiner Hama during a telephone interview on August 10, 2006. It is believed that the present amendment and response overcomes the current rejections as discussed below.

#### 35 U.S.C. § 101

Claims 1-20 stand rejected as purportedly not being supported by either a credible, specific, and substantial utility or a well established utility. That rejection is respectfully traversed to the extent the rejection applies to the claims as amended.

Applicants note that claims 1 and 11, as amended herein, require that the androgen receptor nucleic acid is expressed in the transgenic mouse in at least one tissue selected from the group consisting of lung, heart, liver, testis, bone, prostate, and kidney, such that the mouse has enhanced expression of androgen receptor relative to a wild type mouse in said at least one tissue. Accordingly, the transgenic mouse of the invention has enhanced expression of androgen receptor relative to wild type mouse in at least one tissue.

As stated in the specification, the transgenic mice of the invention provide a model system to monitor activity of androgen receptor in different organs and tissues. The cells in which the nucleic acid reporter is expressed can be readily determined by bioluminescence imaging techniques. These transgenic mice are useful for the development of agents for the treatment of disorders associated with aberrant, up-regulated androgen expression relative to a wild type mouse. In particular, agents can be screened to find those that inhibit or activate the activity of the androgen receptor as measured by the reporter.

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In the Office Action, the Examiner purports that the claimed invention is not supported by a credible, specific, and substantial utility or a well established utility. Applicants respectfully disagree.

As stated in the Office Action mailed December 29, 2005: a credible utility is one that a person of ordinary skill in the art would accept as currently available; a specific utility is one that is specific to the subject matter claimed; and a substantial utility is one that defines a real world use.

The claimed invention has the credible, specific, and substantial use of studying the tissue selective activity of pharmacological agents by inhibition or activation of androgen receptor in different organs and tissues. This is not a study of the properties of the transgenic mouse itself but, rather, a study of the ability of an agent to inhibit or activate androgen receptor expression. This use is both credible and specific given that, as is well known in the art and stated in the specification, the androgen receptor is a hormone regulated transcription factor that controls the expression of many genetic programs involved in normal physiological processes as well as in pathological conditions such as cancer. In addition, this is a substantial utility in that it is a real world use (i.e., identification of androgen receptor modulating agents for the treatment of androgen receptor mediated disorders) rather than studying the properties of the claimed product itself. Applicants also submit that the claimed invention is supported by a well established utility.

Accordingly, it is submitted that this rejection is improper and withdrawal of this rejection is requested.

**35 U.S.C. § 112, first paragraph**

Claims 1-20 stand rejected as purportedly failing to comply with the enablement requirement. That rejection is respectfully traversed to the extent the rejection applies to the claims as amended.

Amended claims 1 and 11 are directed to transgenic mice. It is submitted that the specification enables one of skill in the art to make and (in view of the arguments above concerning the rejection under 35 U.S.C. § 101) use the claimed invention. Withdrawal of this rejection is requested.

**35 U.S.C. § 112, second paragraph**

Claim 7 stands rejected as purportedly being indefinite. It is respectfully submitted that claim 7, as amended herein, is not indefinite. Withdrawal of this rejection is respectfully requested.

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### CONCLUSION

In view of the foregoing amendments and remarks, allowance of the application is respectfully requested. The Examiner is invited to contact the undersigned if there are any questions concerning the prosecution of this application.

The Commissioner is authorized to charge Deposit Account 19-3880 (Bristol-Myers Squibb Company) for any requisite fees due or to credit any overpayment.

Respectfully submitted,

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